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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
VIVLEMORE, TRACY ANN	
ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 06/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/757,298	ANDREWS ET AL.	
	Examiner	Art Unit	
	Tracy Vivlemore	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-40* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, 8-12 and 38, drawn to oligomeric compounds comprising a plurality of 2' hydroxyl ribonucleosides and a protected phosphate group at the 5' terminus wherein the protected phosphate is (S-acetyl-2-thioethyl) phosphate, classifiable in class 536, subclass 24.5.

II. Claims 1-4, 6-12 and 38, drawn to oligomeric compounds comprising a plurality of 2' hydroxyl ribonucleosides and a protected phosphate group at the 5' terminus wherein the protected phosphate comprises a 7-methylguanosine residue attached to the 5' position by a triphosphate linkage in the reverse orientation, classifiable in class 536, subclass 24.5.

III. Claims 1-4, 8-19 and 38, drawn to oligomeric compounds comprising a plurality of 2' hydroxyl ribonucleosides and a protected phosphate group at the 5' terminus having an R_2 group that is (S-acetyl-2-thioethyl phosphate), classifiable in class 536, subclass 24.5.

IV. Claims 1-4, 8-18, 20 and 38, drawn to oligomeric compounds comprising a plurality of 2' hydroxyl ribonucleosides and a protected phosphate group at the 5' terminus having an R_2 group that is straight or branched C_1-C_{12} alkyl or cyano C_1-C_{12} alkyl, classifiable in class 536, subclass 24.5.

V. Claims 1-4, 8-18, 21 and 38, drawn to oligomeric compounds comprising a plurality of 2' hydroxyl ribonucleosides and a protected phosphate group at

the 5' terminus having an R_2 group that is cyanoethyl, classifiable in class 536, subclass 24.5.

VI. Claims 1-4, 8-18, 22 and 38, drawn to oligomeric compounds comprising a plurality of 2' hydroxyl ribonucleosides and a protected phosphate group at the 5' terminus having an R_2 group that is the structure shown in claim 22, classifiable in class 536, subclass 24.5.

VII. Claims 1-4, 8-18, 23-25 and 38, drawn to oligomeric compounds comprising a plurality of 2' hydroxyl ribonucleosides and a protected phosphate group at the 5' terminus having an R_2 group that is the structure shown in claim 23, classifiable in class 536, subclass 24.5.

VIII. Claims 1-4, 8-18, 26 and 38, drawn to oligomeric compounds comprising a plurality of 2' hydroxyl ribonucleosides and a protected phosphate group at the 5' terminus having an R_2 group that is the structure shown in claim 26, classifiable in class 536, subclass 24.5.

IX. Claims 1-4, 8-18, 27 and 38, drawn to oligomeric compounds comprising a plurality of 2' hydroxyl ribonucleosides and a protected phosphate group at the 5' terminus having an R_2 group that is the structure shown in claim 27, classifiable in class 536, subclass 24.5.

X. Claims 1-4, 8-18, 28 and 38, drawn to oligomeric compounds comprising a plurality of 2' hydroxyl ribonucleosides and a protected phosphate group at the 5' terminus having an R_2 group that is the structure shown in claim 28, classifiable in class 536, subclass 24.5.

XI. Claims 1-4, 8-18, 29 and 38, drawn to oligomeric compounds comprising a plurality of 2' hydroxyl ribonucleosides and a protected phosphate group at the 5' terminus having an R_2 group that is the structure shown in claim 29, classifiable in class 536, subclass 24.5.

XII. Claims 1-4, 8-18, 30-32 and 38, drawn to oligomeric compounds comprising a plurality of 2' hydroxyl ribonucleosides and a protected phosphate group at the 5' terminus having an R_2 group that is the structure shown in claim 30, classifiable in class 536, subclass 24.5.

XIII. Claims 1-4, 8-18, 33 and 38, drawn to oligomeric compounds comprising a plurality of 2' hydroxyl ribonucleosides and a protected phosphate group at the 5' terminus having an R_2 group that is the structure shown in claim 33, classifiable in class 536, subclass 24.5.

XIV. Claim 34, 39 and 40, drawn to a method of inhibiting expression of a nucleic acid molecule encoding a target, classifiable in class 514, subclass 44.

XV. Claims 35 and 36, drawn to a method of screening for a modulator of a target, classifiable in class 435, subclass 6.

XVI. Claim 37, drawn to a diagnostic method to identify a disease state, classifiable in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

1. Inventions I-XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects. Each of inventions I-XIII is directed to an oligomeric compound containing a protected phosphate group. The protected phosphate groups each have different chemical structures that impart different physical characteristics to an oligonucleotide such as differing levels of nuclease resistance or differing chemical reactivities.

2. Furthermore, searching any of inventions I-XIII together would impose a serious search burden. In the instant case, prior art searches of oligonucleotides having a protected phosphate group having a specific chemical structure are not coextensive with prior art searches of oligonucleotides having a protected phosphate group having any other specific chemical structure. Search of each of these inventions would require different key word searches of each compound using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of any of inventions I-XIII together.

3. The group of inventions I-XIII is related to invention XIV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product could be used in a materially different process, for example in *in vitro* hybridization assays.

4. Furthermore, searching inventions I-XIII together with invention XIV would impose a serious search burden. In the instant case, prior art searches of oligonucleotides comprising ribonucleosides and a protected phosphate group are not coextensive with prior art searches of methods of inhibiting expression of a nucleic acid molecule encoding a target in cells. Search of each of these inventions would require different key word searches of each compound and of each distinctive step of the method using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of any of inventions I-XIII together with invention XIV.

5. Inventions I-XIII and invention XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. Inventions I-XIII are oligomeric compounds while the function of invention XV is to screen for modulators of a target.

6. Furthermore, searching inventions I-XIII together with invention XV would impose a serious search burden. In the instant case, prior art searches of oligonucleotides comprising ribonucleosides and a protected phosphate group are not coextensive with prior art searches of methods of screening for compounds that modulate a target. Search of each of these inventions would require different key word searches of each compound and of each distinctive step of the method using divergent patent and non-

patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of any of inventions I-XIII together with invention XV.

7. Inventions I-XIII are unrelated to invention XVI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. Inventions I-XIII are oligomeric compounds while the function of invention XVI is to identify a disease state.

8. Furthermore, searching inventions I-XIII together with invention XVI would impose a serious search burden. In the instant case, prior art searches of oligonucleotides comprising ribonucleosides and a protected phosphate group are not coextensive with prior art searches of diagnostic methods of identifying a disease state. Search of each of these inventions would require different key word searches of each compound and of each distinctive step of the method using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of any of inventions I-XIII together with invention XVI.

9. Inventions XIV and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In

the instant case the different inventions have different functions. The function of invention XIV is to inhibit expression of a nucleic acid molecule encoding a target while the function of invention XV is to screen for modulators of a target.

10. Furthermore, searching invention XIV together with invention XV would impose a serious search burden. In the instant case, prior art searches of methods of inhibiting expression of a nucleic acid molecule encoding a target are not coextensive with prior art searches of methods of screening for compounds that modulate a target. Search of each of these inventions would require different key word searches of each compound and of each distinctive step of the method using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of inventions XIV and XV together.

11. Inventions XIV and XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention XIV is to inhibit expression of a nucleic acid molecule encoding a target while the function of invention XVI is to identify a disease state.

12. Furthermore, searching invention XIV together with invention XVI would impose a serious search burden. In the instant case, prior art searches of methods of inhibiting expression of a nucleic acid molecule encoding a target are not coextensive with prior art searches of diagnostic methods of identifying a disease state. Search of each of

these inventions would require different key word searches of each compound and of each distinctive step of the method using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of inventions XIV and XVI together.

13. Inventions XV and XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention XV is to screen for modulators of a target while the function of invention XVI is to identify a disease state.

14. Furthermore, searching invention XV together with invention XVI would impose a serious search burden. In the instant case, prior art searches of methods of screening for modulators of a target are not coextensive with prior art searches of diagnostic methods of identifying a disease state. Search of each of these inventions would require different key word searches of each compound and of each distinctive step of the method using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of inventions XV and XVI together.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note

that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:45-5:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Tracy Vivlemore
Examiner
Art Unit 1635

TV
June 10, 2005

JAMES SCHULTZ
PATENT EXAMINER